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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,429	08/02/2001	Lars Morch Groth	NN-6200.200 US	3993

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PATENT DEPARTMENT
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NEW YORK, NY 10036

EXAMINER

PICKETT, JOHN G

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 01/30/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/921,429

Applicant(s)

GROTH, LARS MORCH

Examiner

Gregory Pickett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 12, 2004 has been entered. Claims 19-22 are pending in the application
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

3. The disclosure is objected to because of the following informalities: Page 8, line 25 cites "cover 6", page 9, line1 cites "cover 6", and "cover 5is", applicant has denoted the cover as item 5 previously.

Appropriate correction is required. Applicant attempted to correct these errors in Amendment B, filed November 24, 2003, however this amendment was not entered due to claim format errors. As such the above informalities remain.

Claim Objections

4. The objection to claim 11 is rendered moot by its cancellation.

Claim Rejections - 35 USC § 112

5. The applicant has canceled claim 12, previously rejected under 35 U.S.C. 112, second paragraph.

6. Claims 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Subset (d.) of claim 19 renders the claim indefinite as the claim depends from a cancelled claim. To examine the claim on its merits, the examiner will ignore the words, "The tool of claim 1, further".

Claim 20 depends from a cancelled claim. To examine the claim on its merits, the examiner assumes the claim to depend from claim 19.

Claim Rejections - 35 USC § 103

7. The applicant has cancelled claims 11-18, previously rejected under 35 U.S.C. 103(a).

8. Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen et al. (US 5,873,462) in view of Current (US 4,203,518).

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Regarding claims 19 and 20, Nguyen et al discloses a tool (10) with a cylinder-shaped base member (30) having a bottom surface (bottom of 30), an upper surface (32), a cylindrical wall surface (outside wall of 30), and spaced cavities (31) containing needle assemblies (100) and having a sterility barrier (150); a cover (20) having a first part (top surface of 20) and a slot (21). The tool of Nguyen provides a means for preventing one directional rotation of the cover in the form of ratchet assemblies (33 and 25) and provides a means for preventing the cover from rotating more than 360 degrees in the form of first protrusion (26) on cover (20) and second protrusion (36) on base member (30). The tool of Nguyen provides a means for preventing rotation (44) of the pen needle while the needle is in the cavity (31). Nguyen et al meets all limitations claimed by the applicant except:

Nguyen et al does not disclose radial extending cavities or a cover with a cylindrical wall.

Current discloses a cover (24) with a second part (28) parallel to a cylindrical wall (20) and a slot (34) provided on the second part (28). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tool of Nguyen et al by rotating the vertical compartments to the horizontal position and providing the magazine with radial extending cavities and a cover as taught by Current in order to reduce the overall height of the container. Such a modification is deemed a mere rearrangement of parts, and it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

With the overall purpose of modification being height reduction, it would have been obvious to one of ordinary skill in the art to limit the height as much as possible. As such, it would have been obvious to limit the magazine height of Nguyen-Current to the width of the cavities (Nguyen et al, Figure 6); thereby creating a total magazine height that is insubstantially greater than the diameter of the needle assembly. The tool of Nguyen-Current is capable of functioning as claimed by the applicant.

Regarding claim 21, the tool of Nguyen-Current, as applied to claim 19 above, provides the claimed tool structure. Nguyen teaches the step of removal of the sterility barrier (Col. 5, lines 30-32). Nguyen teaches the manual application of the needle assembly onto the injection device and therefore inherently discloses the grasping of the tools in the users hands. Nguyen anticipates a screw connection (Col. 5, lines 36-38) and therefore the rotation of the injection device and tool for connection. The specific degree of rotation required would depend on the depth of the thread engagement and is deemed an obvious matter of design choice.

Regarding claim 22, the tool of Nguyen-Current, as applied to claim 19 above, discloses the claimed invention.

Response to Arguments

9. Applicant's arguments filed November 24, 2003 have been fully considered but they are not persuasive.

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10. In response to applicant's argument that neither Nguyen nor Current teach or suggest a tool with increased leverage for rotational assembly of a needle assembly to an injection device, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

11. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation can be found in the knowledge that was generally available to one of ordinary skill in the art at the time the invention was made, where it was a well established principal of design for portable objects to limit overall size. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

12. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that

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any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

13. In response to the applicant's arguments of unexpected results, the examiner has thoroughly considered the arguments in accordance with MPEP § 716.02(c) and 716.01(d) and finds the arguments not persuasive. Evidence of unexpected results must be weighed against evidence supporting *prima facie* obviousness in making a final determination of obviousness of the claimed invention. *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978). Although the record may establish evidence of secondary considerations which are indicia of nonobviousness, the record may also establish such a strong case of obviousness that the objective evidence of nonobviousness is not sufficient to outweigh the evidence of obviousness. *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 769, 9 USPQ2d 1417, 1427 (Fed. Cir. 1988), cert. denied, 493 U.S. 814 (1989); *Richardson-Vicks, Inc., v. The Upjohn Co.*, 122 F.3d 1476, 1484, 44 USPQ2d 1181, 1187 (Fed. Cir. 1997) (showing of unexpected results and commercial success of claimed ibuprofen and psuedoephedrine combination in single tablet form, while supported by substantial evidence, held not to overcome strong *prima facie* case of obviousness). See *In re Piasecki*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984) for a

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detailed discussion of the proper roles of the examiner's *prima facie* case and applicant's rebuttal evidence in the final determination of obviousness.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory Pickett whose telephone number is 703-305-8321. The examiner can normally be reached on Mon-Fri, 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 703-308-2672. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.


Gregory Pickett
Examiner
January 22, 2004



Mickey Yu
Supervisory Patent Examiner
Group 3700